DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

94679d

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

MAY 7 2004

WARNING LETTER

VIA FEDERAL EXPRESS

Robert D. Irons
Vice President
Colema Boards® of California
P.O. Box 1879
Cottonwood, California 96022

Dear Mr. Irons:

We are writing to you because a review of your web site http://www.colema-boards.com revealed a serious regulatory problem involving the product known as "Colema Board®," which is made and marketed by your firm.

Under a United States law, the Federal Food, Drug, and Cosmetic Act (the Act), this product is considered to be a medical device because it is used to diagnose or treat a medical condition or to affect the structure or function of the body of man. The law generally requires that manufacturers of medical devices obtain marketing clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that newly introduced medical devices are safe and effective or substantially equivalent to other devices already legally marketed in this country.

According to your web site, the Colema Board is a home enema kit. An enema kit is a Class I device "intended to instill water or other fluids into the colon through a nozzle inserted into the rectum to promote evacuation of the contents of the **lower colon**." 21 CFR § 876.5210 (emphasis added). You are promoting the Colema Board for evacuation of both the lower and upper colon, in addition to other indications. Your device is therefore not an "enema kit" under 21 CFR § 876.5210 and may not be marketed without clearance from FDA. Additionally, you should be aware that, many of the claims on your web site resemble those for a colonic irrigation system (21 CFR § 876.5220(b)(2)), a Class III prescription device.

Our records do not show that you obtained marketing clearance before you began offering your product for sale. The kind of information you need to submit in order to obtain this clearance is described on FDA's device web site at www.fda.gov/cdrh/devadvice. FDA will evaluate this information and decide whether your product may be legally marketed.

Because you do not have marketing approval or clearance from the FDA, marketing your product is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your product is misbranded under the Act because you did not submit a section 510(k) premarket notification that shows your device is substantially equivalent to other devices that are legally marketed. Until you submit a section 510(k) premarket notification and FDA reviews it and notifies you that you may market your device, your product is also adulterated under the Act because the law requires, and you do not have, an approved premarket approval application that shows your device is safe and effective. For a product requiring premarket approval, the notification required by section 510(k) of the act is deemed to be satisfied when a premarket approval application (PMA) is pending before the agency. 21 CFR 807.81(b).

Your Colema Board® is also misbranded under section 502(o) of the Act, in that the device was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510, was not included in a list required by section 510(j), and a notice or other information respecting your device was not provided as required by section 510(k).

Additionally, your firm may be using latex tubing in the manufacture of the device. The "Board Setup" diagram on your web site indicates items J and K are composed of "Latex surgical tubing," and item L is "Latex-filled U tubing." Devices composed of or containing natural rubber latex must bear the following statement in bold print on the device labeling, in accordance with 21 CFR 801.437(d): "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions." This statement shall appear on all device labels, and other labeling, and shall appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper. Failure to include this caution misbrands the device under section 502 of the Act.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary to take action on this matter now. Please let this office know what steps you have taken to correct the problem within fifteen (15) working days from the date you received this letter. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Mr. Paul Tilton, Chief, OB/Gyn, Gastroenterology and Urology Devices Branch (HFZ-332), Division of Enforcement A, Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Road, Rockville, Maryland 20850.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains to only to the issue of premarket clearance for your device and does not necessarily address other obligations you have under the law.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

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Cc: HFA-224
HFC-134
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HFR-PA1 (BHolman)
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HFR-PA150 (CMoss)
HFZ-220 (DSMICA)
HFZ-300
HFZ-320 (Board Copy)
HFZ-332 (OB/GYN)
HFZ-470 (CNeuland/KOlvey)
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